UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/269,903	05/06/99	WATTS P	WC131

HM12/0824

PATREA L. PABST
HOLLAND & KNIGHT LLP
1201 WEST PEACHTREE STREET
ONE ATLANTIC CENTER, SUITE 2800
ATLANTIC GA 30309-3400

EXAMINER	
CHOI,F	
ART UNIT	**PAPER NUMBER**
1616	17

DATE MAILED: 08/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/269,903	WATTS, PETER JAMES	
	Examiner	Art Unit	
	Frank I Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,19 and 21-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,19 and 21-26* is/are rejected.

7)☒ Claim(s) *27,28* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Objections

Claims 27, 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims subject to update of the prior art search herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17, 19, 21-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions comprising pellets, ridogrel and similar molecules described in U.S. 4, 963,573 and sodium cromoglycate, drugs having a free acid group and a pKa in the range of 2.0-9.0 and adaptation wherein the adaptation is the use of the disclosed coating compounds and a inner core does not reasonably provide enablement a thromboxane synthase A2 inhibitor or a thromboxane A2/prostaglandin endoperoxide receptor antagonist or other adaptations. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. As indicated above, the Specification appears to give limited direction as to the suitable components of the claimed invention. As such, it appears that a skilled artisan would be required to do undue experimentation in order to determine what other

compounds have the desired characteristics of the invention, including whether a drug is thromboxane synthase A2 inhibitor or a thromboxane A2/prostaglandin endoperoxide receptor antagonist, or whether the coating compound will prevent release of the drug until it reaches the colon.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

A specification which describes the invention does not necessarily also enable one of ordinary skill in the art to make or use the claimed invention. See In re Armbruster, 185 USPQ 152 (CCPA 1975). Given that a given membrane must be of sufficient thickness, pH solubility and non-degradeability to pass through the stomach and small intestines but be able to be dissolved/disintegrated in the colon, other than the examples provided, one of ordinary skill in the art would have to do undue experimentation in order to determine what other membranes would be suitable to make and/or use the claimed invention and the appropriate thickness, pH solubility and degradibility. Second, describing a compound by its function does not appear to sufficient indicate what compounds would or would not fall within the scope of said description. As such, one of ordinary skill in the art would have to do undue experimentation in order to determine which compounds fall within or do not fall within the scope of said description.

Claims 1-17, 19, 21-26 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting one or more of the following essential elements or steps, such omission amounting to a gap between the elements or steps. See MPEP § 2172.01. The omitted elements or steps are: a rate controlling membrane which prevents release of the drug until the composition reaches the colon which is determined by the type of coating compound, its pH

solubility and thickness (See Claims 1-17, 19, 21-26), an effective amount of a drug which is effective in treating the claimed intestinal diseases (See Claim 19).

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Although pH solubility and degradability may be inherent properties, thickness of the membrane is not inherent and, in fact, can have an effect on pH solubility and degradability as the thicker the membrane the longer it takes for the enzymes and acid to leach into the membrane and dissolve/disintegrate the membrane. Further, the type of the membrane, its pH solubility and thickness appear to be critical as the composition must be able to pass through the stomach, small intestines to reach the colon. Second, with respect to Claim 19, Examiner suggests using "an amount of drug effective to treat said intestinal diseases" or similar language. Examiner is not requiring Applicant to recite specific dose ranges.

Claim 6 recites "EUDRAGIT^{TM} NE30D" which renders the claim indefinite as trademarks identify the source, i.e. the manufacturer, and not the composition or compound, which formulation is subject to change by the manufacturer. Examiner has duly considered Applicant's arguments but deems them unpersuasive. Again the trademark does not identify composition or compound only the manufacturer. The formulation represented by "NE30D" is subject to change by the manufacturer. Examiner suggests using generic terminology.

Claim 13 recites the phrase "which capsule is so designed to disintegrate and release the pellets" which renders the claim indefinite as it is uncertain how the combination of polymethacrylates are designed to disintegrate and release the pellets. Examiner has duly considered Applicant's arguments but deems them unpersuasive. It is still uncertain how the combination of polymethacrylates are designed to disintegrate and release the pellets.

Claims 15, 16 and 23 contain the phrase "wherein the inner core of the pellets is coated with a rate-controlling membrane . . . coating the salt onto the inner cores, and coating the rate-controlling membrane . . . onto the salt" which renders the claims indefinite as it is uncertain how the inner core can be coated with a rate-controlling membrane when the method limitations indicate that the rate-controlling membrane coats the salt which coats the inner core.

Claim 21 recites the phrase "coated with a material" which renders the claim indefinite as it is uncertain what the tablet is coated with. Examiner has duly considered Applicant's arguments but deems them unpersuasive. It still uncertain what material is used to coat the tablets.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4-12, 14-17, 19, 23 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Juch.

Juch expressly discloses composition and method of administration thereof comprising a pellet, which can be administered in capsules, wherein the pellet contains an inert core, sodium salt of diclofenac coated on said core, and a membrane layer containing ethylcellulose and/or methacrylates falling within the scope of applicant's claims (See Column 7, lines 30-68, Column 8, lines 1-45, Column 9, lines 12-68, Column 10-16.

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See In re May, 197 USPQ 601, 607 (CCPA 1978). See also Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (Bd Pat. App. & Inter. 1993).

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

In the first instance, in an inherency-base rejection under 102/103 the Graham v. John Deere factors are inapplicable, as such, Applicant's arguments relative to what one of ordinary skill would expect or obvious do not appear to overcome the rejections herein. Further, Applicant's claims claim generally that the compositions are adapted to prevent release of drug until the composition reaches the terminal ileum or colon without indicating specifically what that adaptation would be. As such, the burden is on Applicant to show the compositions in Juch do not fall within the scope of the claimed invention. Applicant's arguments relative to Figures 2 and 3 in Juch does not appear to overcome the rejection herein as Applicant's arguments are based on assumptions which may or may not be accurate and different tests appear to be involved.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628.

FIC

August 23, 2001

JOHN PAK
PRIMARY EXAMINER
GROUP 1600